



**UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/043,813	09/29/98	KELLY	M 85010340301

000500 HM12/1220  
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EXAMINER

GUPTA, A

ART UNIT PAPER NUMBER

1653

DATE MAILED: 12/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/043,813

Applicant(s)

Kelly et al.

Examiner

ANISH GUPTA

Group Art Unit

1653



☒ Responsive to communication(s) filed on Nov 9, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-6 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-6 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

### DETAILED ACTION

1. The request filed on 11-09-00 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 16 is acceptable and a CPA has been established. An action on the CPA follows.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Double Patenting*

3. Claims 1-4 and 5-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 54 of U.S. Patent No. 5,962,407. Although the conflicting claims are not identical, they are not patentably distinct from each other because .

Applicants argue that the claims 54 of the US patent is drawn to a pharmaceutical formulation, whereas the claims of the instant application are drawn to compounds. "[T]he pharmaceutical formulations are directed to composition that include various derivatives of isolated compounds; not the compounds themselves." Applicants argue that one could, for instance, prepare a derivative of a compound according to the synthetic methodology disclosed in, for example, Example A4( col. 14, lines 26 to col. 16, line 39) of the issued patent, and then formulate that derivative into a pharmaceutical composition, while never generating or handling the 'isolated compounds' *per se*."

Applicant's arguments filed 11-09-00 have been fully considered but they are not persuasive.

As stated in the previous office, claim 54 recites "A pharmaceutical composition comprising a *compound*, derivative or salt of any claims 1-4, 9-12, 25-31, or 34-40 and a pharmaceutically acceptable carrier." Therefore the claim clearly envisions the isolation of the compound to achieve the pharmaceutical formulation and further distinguishes between the compound and its derivatives or salts since the claims recites all three. Furthermore, Applicants seem to be limiting the scope of the US Patent to a specific method for obtaining the pharmaceutical formulation. However, the claims do not recite such a limitation. They are open to any method of making such a pharmaceutical formulation. Note that in the US Patent, pharmaceutical formulations can be made by "Formula (A or B) in admixture or otherwise in association with one or more carriers." (See col. 10, lines 46-49). Thus this method


clearly envisions handling the "isolated compounds". Thus, there are method of making pharmaceutical formulations that would utilize "isolated compounds" per se.

Further, Note that claim 55 also recites the use of "a therapeutically effective amount of a compound" for the treatment of a patient afflicted with a bacterial function. Therefore claim 55 also envisions the use of a compound, in addition to the derivatives and salts to practice the method.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anish Gupta

  
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